

## **NOVARTIS COMMUNICATION TO HEALTHCARE PROVIDERS REGARDING REVISED ELIDEL<sup>®</sup> (PIMECROLIMUS) CREAM 1% LABEL**

The U.S. Food and Drug Administration (FDA) has updated the prescribing information for ELIDEL (pimecrolimus) Cream 1%, to include a boxed warning and medication guide. A "Dear Doctor" letter will also be distributed.

The well-being of patients is our primary concern at Novartis. We have worked closely with the FDA to revise the prescribing information to address the agency's concerns and refocus our efforts on helping patients effectively manage their eczema.

Your patients may be contacting you regarding their ELIDEL therapy. Decisions regarding treatment with ELIDEL need to be made by you, the practicing physician. Novartis remains confident in the safety of ELIDEL.

Novartis believes that the FDA's decision to include a boxed warning and medication guide is not supported by scientific evidence. This action may cause unnecessary concern among patients and could further limit treatment choices for patients suffering from eczema.

ELIDEL is one of the most thoroughly researched dermatology products in the world. Clinical studies in more than 21,000 patients, including 3500 infants and 7500 children, and experience in more than 6 million patients worldwide show that ELIDEL has a favorable safety profile and is not associated with an increased risk of malignancy. In fact, the revised label states that a causal link has not been established between the use of ELIDEL and skin malignancy or lymphoma.

Support for the safety of ELIDEL and topical calcineurin inhibitors in general has been expressed by many professional associations and societies, including The American Academy of Dermatology (AAD), The American Academy of Asthma, Allergy and Immunology (AAAAI) and The American College of Asthma, Allergy and Immunology (ACAAI), as well as by a number of leading groups representing patients and their families, such as The National Eczema Association for Science and Education (NEASE) and The Inflammatory Skin Disease Institute (ISDI).

The FDA's concerns about the safety of topical calcineurin inhibitors are based on a theoretical risk stemming from the adverse events associated with the systemic use of calcineurin inhibitors in animal studies and transplant patients. These adverse events are associated with intense and prolonged systemic immunosuppression. This effect cannot be achieved with the topical application of ELIDEL Cream in patients with eczema. The absorption of ELIDEL Cream through the skin is so low that in most blood samples studied it was not possible to measure the amount of the active ingredient entering the bloodstream.

ELIDEL provides an important alternative when topical corticosteroids are not advisable such as for patients who have side effects from steroids or suffer from eczema on the face, neck, and/or other sensitive skin areas.

The boxed warning states:

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**“Long-term Safety of Topical Calcineurin Inhibitors Has Not Been Established.**

Although a causal relationship has not been established, rare cases of malignancy (e.g. skin and lymphoma) have been reported in patients treated with topical calcineurin inhibitors, including ELIDEL Cream. Therefore:

- Continuous long-term use of topical calcineurin inhibitors, including ELIDEL Cream, in any age group should be avoided, and application limited to areas of involvement with atopic dermatitis
- ELIDEL Cream is not indicated for use in children less than 2 years of age”

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The wording of the indication has also been revised as follows: “ELIDEL is indicated as *second-line therapy* for the short-term and noncontinuous, chronic treatment of mild to moderate atopic dermatitis in nonimmunocompromised adults and children 2 years of age and older who have failed to respond adequately to other topical prescription treatments, or when those treatments are not advisable.”

If you have any questions regarding this issue please speak with your Novartis representative or call 888-NOW-NOVA.

Novartis remains committed to the safety of patients and we thank you for your attention. The most common adverse events seen in clinical studies included application-site burning, headache, pharyngitis, nasopharyngitis, cough, influenza, pyrexia, and viral infection.

Treatment with ELIDEL should be discontinued upon resolution of symptoms. Patients should be reevaluated if symptoms persist beyond 6 weeks or worsen at anytime.

Please see complete Prescribing Information provided separately.

